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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,241	09/16/2003	Pal Maliga	RUT.97-0097US1-DIV	5658
110 7590 12/11/2007 DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			EXAMINER KUBELIK, ANNE R	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,241	Applicant(s) MALIGA ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-9 and 11 are pending. Claims 1-4 are withdrawn from consideration as being drawn to non-elected inventions.
2. This application contains claims 1-4 drawn to an invention nonelected with traverse in the response filed 18 August 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claim 5 under 35 U.S.C. 102(e) as being anticipated by Maligá et al (US Patent 5,877,402, filed January 1994), taken with the evidence of Legen et al (2002, Plant J. 31:171-188) is withdrawn in light of Applicant's amendment of the claim.

Claim Rejections - 35 USC § 112

5. Claims 5-9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 21 March 2007, as applied to claims 10-11, due to Applicant's amendment of the claims. Applicant's arguments filed 21 September 2007 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the tobacco atpB NEP promoter, barley rpoB NEP promoter, barley clpP NEP promoter or clpP PEP promoters from plant species other than rice.

Thus, such promoters constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the promoters or to cancel the new matter.

Applicant urges that the claims have been amended to recite NEP promoters from Example I and Figure 5, and that support for the amendments can also be found in claims 10-11 as originally presented and Example IV (response pg 5 and 4).

This is not found persuasive. Figure 5 only provides support for the following NEP promoters: atpB from maize, sorghum, barley, wheat, and rice; rpoB from maize and rice; and clpP from maize, rice, and wheat. The only sequences discussed in Example I are from Figure 5.

As stated in the previous new matter rejection, claims 10-11 contained new matter, and thus cannot provide support for the current amendments.

Example IV only provides support for the rbcL, atpB, clpP and 16SrDNA PEP promoters from rice.

6. Claims 5 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 21 March 2007, due to Applicant's amendment of the claims. Applicant's arguments filed 21 September 2007 have been fully considered but they are not persuasive.

The claims require the following the following NEP promoters: atpB from maize, sorghum, barley, wheat, tobacco, or rice; rpoB from maize, rice, tobacco, or barley; or clpP from a plant maize, rice, tobacco, barley, or wheat, and the following PEP promoters: Prn or rice rbcL, maize rbcL, maize atpB, clpP, or barley 16SrDNA. The clpP PEP promoters can be from any source.

The specification fails to describe the structural features of the tobacco atpB NEP promoter, the barley rpoB NEP promoter, the barley clpP NEP promoter, the rice and maize rbcL PEP promoters, the maize atpB PEP promoter, the barley 16SrDNA PEP promoter, or clpP PEP promoters from plant species other than rice.

The level of skill and knowledge in the art at the time of filing was such that only a few of such promoters were identified; thus, there is no well-developed field of prior art.

The specification describes a NEP promoter consensus that is present in some, but not all NEP promoters (pg 21-22). No PEP consensus is described. Thus, the necessary and sufficient structural elements of the claimed promoters are not described within the full scope of the claims.

Hence, Applicant has not, in fact, described nucleic acids that comprise NEP and PEP promoters within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that the claims have been amended to recite NEP promoters from Example I and Figure 5 (response pg 5).

This is not found persuasive because Figure 5 only describes the following NEP promoters: *atpB* from maize, sorghum, barley, wheat, and rice; *rpoB* from maize and rice; and *clpP* from maize, rice, and wheat. The only sequences discussed in Example I are from Figure 5.

7. Claims 5 and 9-10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain constructs comprising both NEP and PEP promoters, does not reasonably provide enablement for all constructs comprising both NEP and PEP promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 21 March 2007. Applicant's arguments filed 21 September 2007 have been fully considered but they are not persuasive.

The claims are broadly drawn to any construct comprising both NEP and PEP promoters, including constructs comprising *clpP*, *rpoB* or *atpB* NEP promoters from any source and/or *rbcL*, *atpB*, *clpP* and 16SrDNA PEP promoters from any source.

The instant specification, however, only provides guidance for analysis of plastid transcription in wildtype and *rpo*⁻ mutants, and the identification of NEP promoters from *clpP*, *rpoB*, *atpB* (example 1), and the PEP promoters from *clpP* (example 2-3); and promoter mapping in rice plastids (example 4).

The instant specification fails to provide guidance for NEP promoters from genes other than *clpP*, *rpoB* and *atpB* from a small number of species, and for PEP promoters from genes other than rice *clpP*.

As the specification does not describe NEP and PEP promoters within the full scope of the claims, undue trial and error experimentation would be required to screen through the myriad

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of nucleic acids encompassed by the claims, to identify those that are NEP and PEP promoters, if such plants are even obtainable.

Applicant urges that Example IV, pg 36 and the reference cited therein fully enables the PEP promoters recited in amended claim 5 (response pg).

This is not found persuasive because Example IV only teaches rice promoters. None of the references cited on pg 36 have been sent, nor are they incorporated by reference.

8. Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the non new matter limitations of the base claim and any intervening claims.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

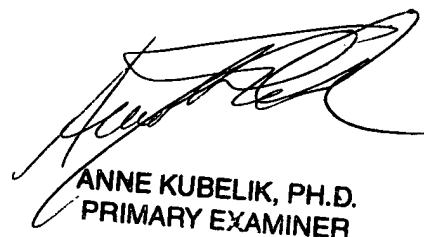
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Anne Kubelik, Ph.D.
December 5, 2007



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER